Message

From: Post, Gloria [Gloria.Post@dep.nj.gov]
Sent: 1/6/2016 6:54:56 PM
Subject: Links to peer reviewers' comments and public comments on the draft ATSDR Toxicological Profile for Perfluoroalkyls

FYI.

1. **Public comments submitted on the ATSDR draft Toxicological Profile for Perfluoroalkyls**
   http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=ATSDR-2015-0004 Aside from NJDEP/NJDOH and Dr. Grandjean (below), all of the comments were from industry-affiliated groups (3M, FluoroCouncil, Chemistry Council of NJ, and Solvay Specialty Polymers/Integral consulting firm).

2. **ATSDR's responses to peer reviewers' comments (dated December 2014) on the peer review draft that preceded the August 2015 draft posted for public comment.**

It appears that the peer reviewers wrote extensive comments on an earlier peer review version, but ATSDR did not incorporate many of their suggestions into the draft they put out for public comment in August 2015.
http://www.atsdr.cdc.gov/sites/peer_review/docs/Disposition_of_Peer_Review_Comments_Perfluoroalkyls.pdf

Additional public comment submitted by Dr. P. Grandjean that is not posted at the Regulations.gov link:

On page 176, a statement is made that the benchmark calculations that I was responsible for (http://www.ehjournal.net/content/12/1/35) did not include a "control group". I believe that this comment is seriously misleading, as the presence of a control group is not a firm requirement for calculating a benchmark dose. Likewise, the draft indicates that model fits were not reported. These comments appear to suggest that our work is not valid and therefore could be properly ignored by ATSDR. However, immunotoxicity may well be the critical effect of these compounds in humans and could likely provide the most appropriate basis for deriving an MRL. In my mind, the wording of the draft suggests that the authors are not familiar with the use of epidemiological data to calculate benchmark doses. If true, I would consider that a serious problem, as human data should be regarded as crucial for a public health assessment.

The fact is that human population studies almost never have access to an unexposed control group. My co-author, Dr. Esben Budtz-Jorgensen and I recently assisted the European Food Safety Authority in developing guidelines for benchmark dose calculations (http://www.efsa.europa.eu/en/efsajournal/pub/1150). For epidemiological studies, we recommend the use of the so-called hybrid model, and we also discuss approaches to calculating the model fits (as was done in our article that was criticized in the ATSDR draft). As we cannot test our model against an "unrestricted" model, we reported the log-likelihood values for several plausible models. The joint result from these models is that the benchmark dose in humans is very low. However, ATSDR chose not to report this information, although supporting evidence from two other population studies is briefly mentioned. Overall, the epidemiological evidence suggests that, to protect against immune toxicity from PFOS and PFOA, exposures would have to be much below current exposure levels and the MRL recommended by ATSDR.

While we generally praise ATSDR's efforts to generate recommendations on pollution abatement and exposure limits (or MRLs), in this case ATSDR ignores the most relevant human toxicity data and recommends exposure limits that will not protect against immune system dysfunction in children exposed to PFASs.